

References

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The effect of ductal diameter on surgical and medical closure of patent ductus arteriosus in preterm neonates

To the Editor:

We read with interest the article by Tschuppert and colleagues¹ on the effect of ductal diameter on surgical and medical closure of patent ductus arteriosus (PDA) in preterm neonates. The question that the study aims to answer is quite relevant. Indeed, PDA is a common and potentially lethal condition in preterm neonates and is associated with significant comorbidities and resource use.² Tschuppert and colleagues¹ suggest that PDA size can be used to predict patients in whom medical management is likely to fail to achieve hemodynamic irrelevance. In particular, they suggest that patients with PDA areas of greater than 9 mm²/kg should be offered primary surgical closure at the time of diagnosis.

We think some comments are worth reporting on the study.

It is known that there is an inverse association between PDA size and the rate of closure after indomethacin administration in premature infants.³ As a consequence, a difference in PDA size between patients who do and those who do not respond to indomethacin would be expected. A surprising result of the present study is that the difference in PDA diameter in patients

who responded to medical treatment (2.4 ± 0.6 mm) and those who did not respond to medical management (2.8 ± 0.9 mm) was extremely low (+16% or 0.4 mm). Even if an average difference of 0.4 mm appears to be significant ($P = .006$) in statistical terms, we question how such a small difference can be clinically significant. This is particularly relevant because the difference in PDA size observed in the 2 groups largely overlaps with the reproducibility error for repeated measurements of similar cardiac structures by means of echocardiography.

Concerning the proposed 9 mm²/kg cutoff value, direct visual assessment of the figure provided suggests that no clear cutoff exists to discern patients who can be managed medically and those who will ultimately require surgical intervention. Accordingly, 19 (49%) of 39 reported patients with a PDA of larger than 9 mm²/kg actually responded to medical treatment alone and would have been erroneously sent to surgical intervention by using the proposed cutoff value. Also, 27 (17%) of the 162 patients with a PDA of smaller than 9 mm²/kg would be erroneously considered medically manageable, thus requiring delayed PDA surgical closure and longer intensive care unit stay.

Overall, we think the present study indicates that no clear cutoff exists to select patients who should undergo primary surgical PDA closure.

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Reply to the Editor:

In their letter Drs Giardini and Derrick summarize the statistical analysis and the findings of our article pertaining to the effect of ductal diameter in preterm babies as diagnosed by means of echocardiographic analysis and its relevance to the choice of therapy and success rate for patent ductus arteriosus (PDA) closure. They conclude that the current data do not indicate a clear cutoff value as to selecting patients for primary surgical PDA closure. I agree with their statement and am relieved that they read the article so carefully because no such pretence is stated anywhere in the text.

First, in the conclusions of the abstract, it is stated that medical treatment is a valid first option, but it is likely to fail with larger PDA diameters and lower birth dates. Furthermore, "hospital stay might be shortened by earlier surgical referral ... index greater than 9 mm²/kg."

In the conclusions of the Discussion section, it is repeated that medical treatment is the valid initial therapy in the absence of contraindications to medication and hemodynamic instability. "Patients with an index of greater than 9 mm²/kg would probably benefit from early direct surgical closure at the end of any given medical protocol...."

Statistical analysis of data, no matter how robust or clear-cut, which is not the case in the present study and is clearly acknowledged as such, cannot replace common sense and good clinical judgment. We have not introduced a new magical number by which a binary decision process should be made, thereby replacing medical treatment for PDA closure in preterm babies. Rather an index is presented, which can serve as a guideline to clinicians dealing with these patients to avoid undue delay in proposing and undertaking surgical PDA ligation.¹

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